



10 of 3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT EXAMINING OPERATION

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In re Application of:
PETER T. PUGLIESE

Serial No.: 09/989,019
Filed: November 21, 2001

Title: THE USE OF COMBINED
FLAVONES AND ISOFLAVONES TO
TREAT CELLULITE

Group Art Unit No.: 1617

Supervisory Examiner:
R. Travers (GP 1200)

Phone No.: (703) 308-3627

Examiner: San-Ming Hui

#12
AKO
5-16-03

Patent & Trademark Office
ATTN: Group 1617
Washington, D.C. 20231

**REPLY BRIEF TO THE BOARD OF APPEALS CONFORMING
WITH 37 C.F.R. §1.193(b)**

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PREAMBLE

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In allowing the sole method of use Claim 8, the Examiner states: "Cited prior art, save Koulbanis and Soudant et al, are silent on treating cellulites[sic]. These anti-cellulites [sic] recitations are not regards [sic] to obviate the claims 1-7, 9-11."

Cellulite is described in the specification on page 1, as the lead paragraph under Background, and will not be reproduced here in the interest of brevity. However, cellulitis is inflammation of cellular or connective tissue; this is not cellulite. See Taber's Medical Dictionary, 1981, page 37. This crucial technical misreading of the now excepted citations of Koulbanis and Soudant has induced the Primary Examiner to rely upon them as citable prior art, when, in fact, they are non-pertinent prior art.

As to the Koulbanis '433 specification, at no place in that specification, the working examples, nor the issued claims is a specific condition CELLULITE (as defined by this Specification) even recited incidentally. Rather, This "slimming action" patent refers solely to "anti-cellulitis action". In each of example I-VI only anti-cellulitis solutions are taught, while example VII is to a slimming cream. None of the active principles of the present emulsion are seen in that prior art cream. Both of the independent method claims there are for the treatment of cellulitis, not cellulite. Indeed, the Koulbanis Specification does not even identify female cellulite as a physical condition that it addresses. Treating the substantially dissimilar condition cellulitis in this patent clearly does not remotely make obvious the here-demonstrated treatment of cellulite now taught.

Soudant et al '230 (1995) is also directed to a slimming composition and claims treatment for slimming of body part having a local fat overload etc. (see Claim 1) with an effective anti-fat amount of at least one growth factor that has lipolytic activity preferably by oral ingestion. This claim's growth factor (all being polypeptide molecules) are recited in a Markush group of EPF, FGF, EDGT, and NTGF. All the emulsions, save a slimming cream, are for oral ingestion. What is the underlying condition being treated? See

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Again, not even an incidental identification of the dissimilar cellulite as the focus of the alternate teaching of Soudant.

As with Koulbanis, using a growth factor in a slimming procedure does not suggest or make obvious the preparation of an oil-in-water emulsion of the present invention for topical skin application. So Soudant is also non-pertinent prior art.

The efficacy of the here claimed formulations shreds any slight presumption that Koulbanis or Soudant might implicitly suggest treatment of cellulite. They do not even identify such in their specifications as being among the objectives of their patent teachings. The lack of anticipatory value of the other six citations is of record in the main brief and is incorporated here by reference.

Electrophoresis technique of Koulbanis vs. oral admission of Soudant vs. a repetitive topical treatment of the present invention here are worlds apart given the basically different formulations disclosed.

The of-record specification showing comprises quantifiable clinical evidence that the disclosed compounds as topical emulsions will produce an appreciable reduction in manifestations of cellulite. Moreover, the of-record R132 Declaration establishes that certain flavones provide a positive effect on treating cellulite. The two relied upon patent citations neither recognize the focused condition, nor do they provide suitable formulations for this purpose, nor even allude to the objectives of the present invention. As with now allowable method claim 8, all of the emulsion claims should be likewise deemed to recite patentable subject matter.

PROBATIVE WEIGHT OF THE OBJECTIVE EVIDENCE OF RECORD

The Primary Examiner has remarkably given short shrift to the objective evidence of the utility and non-obviousness of these formulations. Since most of the working examples of either Koulbanis or Soudant do not describe an oil-in-water emulsion containing many of the active compounds of the present emulsion, a directly comparative showing of the preferred species, genistein, could not be proffered below.

As stated in the 1979 CCPA decision of *In re Carlton*:

“If the applicant presents rebuttal evidence, the decision-maker must consider all of the evidence of record (both that supporting and that rebutting the *prima facie* case) in determining whether the subject matter of the whole would have been obvious. [footnote admitted *In re Rinehart*, 531 Fed. 2d 1048, 89 USPQ 143 (CCPA 1976); *In re Lewis*, 443 Fed. 2d 389, 170 USPQ 84 (CCPA 1971). The correct procedure for considering rebuttal evidence was set forth by this court in *In re Rinehart*, *supra* at 1052, 189 USPQ at 147.”

With regard to the claimed Markush grouping in claim 1, it has been held that the unobviousness of a broader claim range can, in certain instances, be proven by a narrower range of data.

See *In re Kollman*, 595 Fed. 2d 48, 201 USPQ 193 (Fed. Cir. 1979). This was a chemical genus case (analogous to the present Markush groupings of flavones, in which the court stated:

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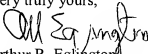
establish the correlation between ortho substitution on the 2-phenyl ring and greatly increased color fading rates.

Moreover, no factual basis appears in the record for the expecting the compounds to behave differently in other environments. Accordingly, we reverse the 103 rejection."

Accordingly, predicated upon the of record Rule 132 declaration showing on efficacy to the genistein species, there is no reason to doubt that other group members, either the recited hydroxy flavones or the isoflavones would not be likewise effective.

Favorable reconsideration and reversal of the final rejection by the Primary Examiner is respectfully solicited.

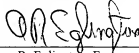
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Appendix: All Claims on Appeal

Very truly yours,

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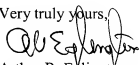
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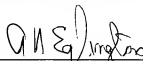
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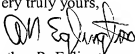
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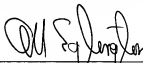
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